# Declaration of Conformity

*Per 93/42 EEC MDD*

| | |
|---|---|
| ***Manufacturer*** | Avery Dennison Medical Ltd. |
| ***Address*** | IDA Business Park,<br>Ballinalee Road,<br>Longford, N39 DX73,<br>Ireland |
| ***Single Registration Number*** | IE-MF-000001926 |
| ***Authorized Representative*** | Not Applicable |
| ***Medical Device Description*** | Silfoam is a sterile, absorbent, self-adherent soft silicone wound dressing. It comprises of a soft silicone skin and wound contact layer, a polyurethane Silfoam layer with low to moderate absorption capacity and a vapour permeable, water and bacteria resistant polyurethane film outer layer. It is available in a border and non-border version.<br><br>In the presence of exudate, Silfoam helps maintain a moist wound environment conducive to natural healing conditions. |

| **Product Name** | **Product Classification** | **Classification Rule** | **Conformity Pathway** | **CE Certificate Number** |
|---|---|---|---|---|
| SilFoam and SilFoam Border (including [redacted] & [redacted] Askina Dressil) | IIb | Rule 4 | Annex IX QMS and Technical Documentation | GB19 964486 |
| Silfoam V and SilFoam V Border | IIb | Rule 4 | Annex IX QMS and Technical Documentation | GB19 964486 |

| | |
|---|---|
| ***Basic UDI-DI*** | 081713801TF009Y6 |
| ***Intended Purpose*** | Long term, non-invasive wound dressings intended principally for the management of light to moderately exuding partial to full thickness wounds which have breached the dermis on injured skin and can only heal by secondary intent. |
| ***Indication*** | Silfoam range is indicated for the management of light to moderately exuding, partial to full thickness wounds. It is indicated for following wounds:<br>• Pressure ulcers |

# Declaration of Conformity

*Per 93/42 EEC MDD*

| | |
|---|---|
| | • Venous & arterial leg ulcers<br>• diabetic foot ulcers<br>• First and second degree burns<br><br>Silfoam may also be used as an aid for prevention of skin breakdown. |
| ***Notified Body*** | 1639 |
| ***Notified Body Number*** | SGS Belgium NV.,<br>SGS House,<br>Noorderlaan 87 2030 Antwerp,<br>Belgium |

# Declaration of Conformity

*Per 93/42 EEC MDD*

Avery Dennison Medical Ltd.; declares that the above documented products meet the provision of the MDD 93/43 EEC. This declaration authorises Avery Dennison Medical to affix the CE-mark to the products listed herein. This declaration is supported by compliance with the general safety and performance requirements by meeting the harmonised standards outlined in Attachment 2.

We, hereby declare that this declaration of conformity is issued under the sole responsibility of Avery Dennison Medical Ltd.

| Name and Title | Signature and Date |
|---|---|
| Elaine Minagh<br>Regulatory Affairs Manager | Captured on Master Control |
| **Place of issue** | **Date of issue** |
| Longford, Ireland | Captured on Master Control |

# Declaration of Conformity

*Per 93/42 EEC MDD*

## Attachment 1: List of Product Codes

**Table 1 Devices covered within the Technical Documentation TF009**

| Description | Size | Units/box | Article Number | CE Certificate Date |
|---|---|---|---|---|
| SilFoam | 5 x 7 cm | 3 | 93050703 | April 2012 |
| SilFoam | 5 x 7 cm | 10 | 93050710 | April 2012 |
| SilFoam | 6.4 x 6.4 cm | 10 | 93060610 | April 2012 |
| SilFoam | 10 x 10 cm | 3 | 93101003 | April 2012 |
| SilFoam | 10 x 10 cm | 5 | 93101005 | April 2012 |
| SilFoam | 10 x 10 cm | 10 | 93101010 | April 2012 |
| SilFoam | 10 x 20 cm | 3 | 93102003 | April 2012 |
| SilFoam | 10 x 20 cm | 5 | 93102005 | April 2012 |
| SilFoam | 10 x 20 cm | 10 | 93102010 | April 2012 |
| SilFoam | 10.2 x 12.7 cm | 10 | 93101310 | April 2012 |
| SilFoam | 15 x 15 cm | 3 | 93151503 | April 2012 |
| SilFoam | 15 x 15 cm | 5 | 93151505 | April 2012 |
| SilFoam | 16.5 x 20.3 cm | 10 | 93172010 | April 2012 |
| SilFoam | 20 x 20 cm | 5 | 93202005 | April 2012 |
| SilFoam Heel | 20.3 x 12.7 cm | 10 | 93201310 | April 2012 |
| SilFoam Border | 4 x 5 cm | 3 | 94040503 | April 2012 |
| SilFoam Border | 4 x 5 cm | 10 | 94040510 | April 2012 |
| SilFoam Border | 5 x 7cm | 3 | 94050703 | April 2012 |
| SilFoam Border | 5 x 7cm | 10 | 94050710 | April 2012 |
| SilFoam Border | 9 x 9cm | 10 | 94090910 | April 2012 |
| SilFoam Border | 10 x 10cm | 3 | 94101003 | April 2012 |
| SilFoam Border | 10 x 10cm | 10 | 94101010 | April 2012 |
| SilFoam Border | 12.7 x 15.7cm | 10 | 94131610 | April 2012 |
| SilFoam Border | 15 x 15cm | 3 | 94151503 | April 2012 |
| SilFoam Border | 15 x 15cm | 10 | 94151510 | April 2012 |
| SilFoam Border | 10 x 20cm | 3 | 94102003 | April 2012 |
| SilFoam Border | 10 x 20cm | 10 | 94102010 | April 2012 |
| SilFoam Border | 18 x 18cm | 10 | 94181810 | April 2012 |
| SilFoam Border | 20 x 20cm | 5 | 94202005 | April 2012 |
| SilFoam Border Sacrum | 18 x 20cm | 5 | 94182005 | April 2012 |
| SilFoam Border Sacrum | 18.6 x 18.8cm | 10 | 94191910 | April 2012 |
| SilFoam Border Sacrum | 23 x 23cm | 5 | 94232305 | April 2012 |
| SilFoam Border Sacrum | 25.5 x 22cm | 10 | 94262210 | April 2012 |
| [redacted] | | | | |
| [redacted] Circular Dressing | 7.5 | 10 | [redacted] | 21st July 2020 |
| Circular Dressing | 15 | 10 | | 21st July 2020 |
| Circular Dressing | 22 | 10 | | 21st July 2020 |
| Square Dressing | 5x6 | 10 | | 21st July 2020 |
| Square Dressing | 9x9 | 10 | | 21st July 2020 |
| [redacted] Silfoam | | | | |
| Silfoam Border 10pcs | 7.5x7.5cm, | 10 | [redacted] | 08 Aug 2022 |
| Silfoam Border 10pcs | 10x10cm, | 10 | | 08 Aug 2022 |
| Silfoam Border, 10pcs | 15x15cm | 10 | | 08 Aug 2022 |
| Silfoam Non-Border | 10x10cm, | 10 | | 08 Aug 2022 |
| Silfoam Non-Border | 20x20cm, | 5 | | 08 Aug 2022 |
| Askina DresSil | | | | |
| Askina® DresSil Non Border | 5 x 7cm | 10 | ADM5295710 | 24 May 2023 |
| Askina® DresSil Non Border | 10 x 10cm | 10 | ADM5291010 | 24 May 2023 |
| Askina® DresSil Non Border | 10 x 20cm | 10 | ADM5291210 | 24 May 2023 |
| Askina® DresSil Non Border | 15 x 15cm | 5 | ADM5291505 | 24 May 2023 |
| Askina® DresSil Non Border | 20 x 20cm | 5 | ADM5292005 | 24 May 2023 |
| Askina® DresSil Border | 6 x 6cm | 10 | ADM5396610 | 24 May 2023 |

# Declaration of Conformity

*Per 93/42 EEC MDD*

**Table 1 Devices covered within the Technical Documentation TF009**

| Description | Size | Units/box | Article Number | CE Certificate Date |
|---|---|---|---|---|
| Askina® DresSil Border | 7.5 x 7.5cm | 10 | ADM5397510 | 24 May 2023 |
| Askina® DresSil Border | 10 x 10cm | 10 | ADM5391010 | 24 May 2023 |
| Askina® DresSil Border | 10 x 20cm | 10 | ADM5391210 | 24 May 2023 |
| Askina® DresSil Border | 15 x 15cm | 10 | ADM5391510 | 24 May 2023 |
| Askina® DresSil Border | 15 x 20cm | 10 | ADM5395210 | 24 May 2023 |
| Askina® DresSil Border | 20 x 20cm | 5 | ADM5392005 | 24 May 2023 |
| Askina® DresSil Sacrum | 16 x 17.5cm | 5 | ADM5491605 | 24 May 2023 |
| Askina® DresSil Sacrum | 21 x 22cm | 5 | ADM5492105 | 24 May 2023 |
| Askina® DresSil Heel | 22 x 21.6cm | 5 | ADM5592205 | 24 May 2023 |

# Declaration of Conformity

*Per 93/42 EEC MDD*

**Attachment 2: List of Harmonized Standards and Common Specifications**

| Standard/Regulation | Title |
|---|---|
| EN ISO 13485 | Medical Devices - Quality Management Systems – Requirements for Regulatory Purposes |
| EN ISO 14971 | Medical devices - Application of risk management to medical devices |
| EN ISO 10993-1 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| EN ISO 10993-5 | Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity |
| EN ISO 10993-10 | Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization |
| EN ISO 10993-7 | Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals |
| EN ISO 11737-1 | Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products |
| EN ISO 11737-2 | Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process |
| BS EN ISO 11135:2014+A1:2019 | Sterilization of health care products - Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices |
| EN 556-1: 2002 | Sterilisation of Medical Devices – Requirements for Medical Devices to be designated sterile - Part 1: Requirements for terminally -Sterile Medical Devices. |
| ISO 11135-1 | Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices |
| EN ISO 14644-1 | Cleanrooms and Associated Controlled Environments – Part1: Classification of Air Cleanliness. |
| EN ISO 14644-2 | Cleanrooms and Associated Controlled Environments - Part 2: Specifications for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1 |
| EN ISO 11607-1 | Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems |
| EN ISO 11607-2 | Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes |
| EN 13726 | Test methods for wound dressings. Aspects of absorption, moisture vapour transmission, waterproofness and extensibility |
| EN ISO 15223 | Medical device - symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements |
| EN 20417 | Information supplied by the manufacturer of medical devices |
| IEC 62366-1 | Medical devices. Application of usability engineering to medical devices |

*Refer to GBL-LST-000006 for current Standard Revision*

# Declaration of Conformity

*Per 93/42 EEC MDD*

**Revision History**

| Revision | Date | Revision History | Originator |
|---|---|---|---|
| A | 11 Jan 2021 | Initial Revision The document is created to maintain compliance to the Regulation 93/42/EEC | N. Gajbhiye |
| B | 22 Feb 21 | 100312 rev b Update to DOC for Silfoam and Silfoam borders to include new product introduction - [redacted] Circular and Square dressings. | D. Casey |
| C | 23 Jan 2023 | Update to include [redacted] codes, remove revisions from table of applied standards<br>Correct title MDD 93/42 EEC | Patricia Slattery |
| D | 07 June 2023 | Addition of Askina Dressil codes, remove UDI, add CE certification date | Patricia Slattery |
| E | 20/05/24 | Correct basic udi from 0081713801TF009KC to 081713801TF009Y6 | Patricia Slattery |
| F | 06 Sept 2024 | Updated to remove word "such as" from indication.<br>Added "arterial leg ulcers" to indication. | A. Boateng |

## Signature Manifest

**Document Number:** LFD-DOC-000020
**Revision:** F
**Title:** MDD DOC, Silfoam
**Effective Date:** 17 Sep 2024

All dates and times are in GMT.

### Silfoam MDD DoC

### Change Request

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Angel Boateng (ANGEL.BOATENG) | Regulatory Affairs Associate | 06 Sep 2024, 02:39:24 PM | Approved |
| Gergely Robert Racz (GERGELY.ROBERT.RACZ) | Documentation Control Specialist | 11 Sep 2024, 03:31:47 PM | Approved |

### Collaboration

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Elaine Minagh (ELAINE.MINAGH) | Regulatory Affairs Manager | 12 Sep 2024, 05:11:41 PM | Complete |
| Angel Boateng (ANGEL.BOATENG) | Regulatory Affairs Associate | 13 Sep 2024, 09:46:28 AM | Complete |

### Originator Approval

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Angel Boateng (ANGEL.BOATENG) | Regulatory Affairs Associate | 13 Sep 2024, 09:47:11 AM | Approved |

### Other Approvals

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Elaine Minagh (ELAINE.MINAGH) | Regulatory Affairs Manager | 13 Sep 2024, 11:18:51 AM | Approved |
| Angel Boateng (ANGEL.BOATENG) | Regulatory Affairs Associate | 13 Sep 2024, 02:01:50 PM | Approved |

### Doc Control Collaboration

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Gergely Robert Racz (GERGELY.ROBERT.RACZ) | Documentation Control Specialist | 17 Sep 2024, 10:22:47 AM | Complete |

### Set Dates

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Gergely Robert Racz (GERGELY.ROBERT.RACZ) | Documentation Control Specialist | 17 Sep 2024, 10:25:05 AM | Approved |

### Notify

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Angel Boateng (ANGEL.BOATENG) | Regulatory Affairs Associate | 17 Sep 2024, 10:25:06 AM | Email Sent |
| Gergely Robert Racz (GERGELY.ROBERT.RACZ) | Documentation Control Specialist | 17 Sep 2024, 10:25:06 AM | Email Sent |

## Quick Approval

## Approve Now

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Gergely Robert Racz (GERGELY.ROBERT.RACZ) | Documentation Control Specialist | 17 Sep 2024, 11:55:28 AM | Approved |

Effective